

CLAIMS

We claim:

1. A method of coating an implantable prosthesis with a layer comprising an hydrophobic elastomeric material incorporating an amount of biologically active material therein for timed delivery therefrom comprising the steps of:

- (a) applying a formulation containing polymeric material in solvent mixture and an amount of finely divided biologically active species;
- (b) curing said polymeric material; and
- (c) wherein the average particle size of the finely divided biological species in said coating formulation is selected to affect delivery kinetics.

2. The method of claim 1 wherein the elastomeric material is selected from the group consisting of silicones, polyurethanes, polyamide elastomers, ethylene vinyl acetate copolymers, polyolefin elastomers, EPDM rubbers and combinations thereof.

3. The method of claim 1 wherein the biologically active material has an average particle size \leq about 15 μm .

4. The method of claim 2 wherein the biologically active material includes heparin.

5. The method of claim 4 wherein the layer comprises about 25-45 weight percent biologically active material.

6. The method of claim 1 wherein the biologically active material has an average particle size $\leq 10 \mu\text{m}$.

7. The method of claim 6 wherein the biologically active material includes heparin.

5 8. A method of controlling the kinetics of an eluting (biologically active) particulate material incorporated in a polymeric coating in an implantable prosthesis comprising the step of controlling the average particle size below a designated maximum size.

10 9. The method of claim 7 wherein said biologically active material is heparin and the average particle size is \leq about $15 \mu\text{m}$.

10 10. The method of claim 9 wherein the layer comprises about 25-45 weight percent biologically active material.

15 11. A method of controlling the kinetics of an eluting (biologically active) particulate material incorporated in a polymer coating in an implantable prosthesis comprising the steps of selecting an average particle size and a drug load to produce desired delivery kinetics.

20 12. The method of claim 11 further comprising the steps of selecting an average particle size and a drug load to produce a substantially smooth surface on the prosthesis.

13. The method of claim 11 wherein the layer comprises about 25-45 weight percent biologically active material.

14. The method of claim 13 wherein said biologically active material is heparin and the average particle size is \leq about 15 μm .

15. A coated implantable prosthesis having an external surface covered with a conformal coating comprising a hydrophobic elastomeric material incorporating an amount of biologically active material in particulate form dispersed therein for timed delivery therefrom wherein the delivery kinetics thereof is controlled at least in part by variations in parameters selected from the group consisting of average particle size and concentration of dispersed material in said coating or a combination thereof.

16. The device of claim 15 wherein the delivery kinetics are controlled by variations in particle size.

17. The device of claim 15 wherein the elastomeric material is selected from the group consisting of silicones, polyurethanes, polyamide elastomers, ethylene vinyl acetate copolymers, polyolefin elastomers, EPDM rubbers and combinations thereof.

18. The device of claim 15 wherein the biologically active material has an average particle size \leq about 15 μm .

19. The device of claim 18 wherein the biologically active material includes heparin.

20. The device of claim 15 wherein the layer comprises about 25-45 weight percent biologically active material.

5 21. The device of claim 15 wherein the biologically active material has an average particle size $\leq 10 \mu\text{m}$.

22. The device of claim 21 wherein the biologically active material includes heparin.

10 23. The device of claim 15 wherein the layer comprises about 25-45 weight percent biologically active material and wherein the biologically active material is heparin having an average particle size ≤ 10 microns.

1005044-00000000